

Substitute for form 1449A-B/PTO

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Application Number	10/549,506
Filing Date	July 7, 2006
First Named Inventor	Kim Vilbour Andersen
Group Art Unit	1653
Examiner Name	Not yet assigned
Attorney Docket Number	0272us310

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	U.S. Patent Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, lines, Where Relevant Passages or Relevant Figures Appeal
	1	5,093,317		Lewis et al.	03-03-1992	
	2	5,258,288		Wydro et al.	11-02-1993	
	3	5,504,064		Morrissey et al.	04-02-1996	
	4	5,516,640		Watanabe et al.	05-14-1996	
	5	5,788,965		Berkner et al.	08-04-1998	
	6	5,817,788		Berkner et al.	10-06-1998	
	7	5,824,639		Berkner	10-20-1998	
	8	5,833,982		Berkner et al.	11-20-1998	
	9	5,837,843		Smirnov et al.	11-17-1998	
	10	5,847,085		Esmon et al.	12-08-1998	
	11	6,100,061		Reiter et al.	08-08-2000	
	12	6,423,826		Nelstestuen et al.	07-23-2002	
	13	6,475,725		Reiter et al.	11-05-2002	
	14	6,693,075		Nelstestuen	02-17-2004	
	15	6,747,003		Nelstestuen	06-08-2004	
	16	6,762,286		Nelstestuen	07-13-2004	
	17	6,806,063		Pedersen et al.	10-19-2004	
	18	6,903,069		Pingel et al.	09-26-2002	
	19	7,026,524		Persson et al.	04-11-2006	
	20	US2003/0100506		Nelstestuen	05-29-2003	
	21	Pending claims of US2003/0100506		Nelstestuen	05-29-2003	
	22	US2003/0100740		Persson et al.	05-29-2003	
	23	US2003/0104978		Persson et al.	06-05-2003	
	24	US2003/0211094		Nelstestuen	11-13-2003	
	25	US2003/0211460		Nelstestuen	11-13-2003	
	26	Pending claims of USSN 10/031,005,		Nelstestuen	Parent application published as	
Examiner Signature	/Samuel Liu/			Date Considered	07/13/2009	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Substitute for form 1449A-B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>	Complete if Known		
	Application Number	10/549,506	
	Filing Date	July 7, 2006	
	First Named Inventor	Kim Vilbour Andersen	
	Group Art Unit	1653	
	Examiner Name	Not yet assigned	
		Attorney Docket Number	0272us310

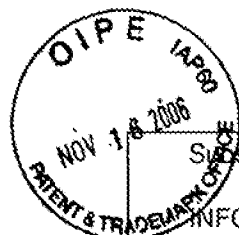
	which is a national phase appn of WO 00/66753, which was cited on previously filed IDS/1449)			WO 00/66753	
--	----------------------------------------------------------------------------------------------	--	--	-------------	--

FOREIGN PATENT DOCUMENTS								
Examiner Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Office	Number	Kind Code (if known)				
	27	WO	02/03075		University of Minnesota	01-10-2002		
	28	WO	02/02764		University of Minnesota	01-10-2002		
	29	WO	02/29025		Novo Nordisk A/S	04-11-2002		
	30	EP	0 296 413	A2	Hoechst Japan	12-28-1988		
	31	EP	0 354 504	A2	Hoechst Japan	02-12-1990		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	32	Amlijots et al., "Prevention of experimental arterial thrombosis by topical administration of active site-inactivated factor VIIa," J. Vasc. Surg., 1997, 25(2):341-346	
	33	Bauer, "Treatment of factor VII deficiency with recombinant factor VIIa," Haemostasis, 1996, 26 (Suppl. 1):155-158	
	34	Broze et al., "Monoclonal anti-human factor VII antibodies. Detection in plasma of a second protein antigenically and genetically related to factor VII," J. Clin. Invest., 1985, 76:937-946	
	35	Choudhri et al., "Targeted Inhibition of Intrinsic Coagulation Limits Cerebral Injury in Stroke without Increasing Intracerebral Hemorrhage," J. Exp. Med., 1999, 190:91-99	
	36	Christiansen et al., "Hydrophobic Amino Acid Residues of Human Anticoagulation Protein C that Contribute to its Functional Binding to Phospholipid Vesicles," Biochemistry, 1995, 34:10376-10382	
	37	Dackiw et al., "Prevention of endotoxin-induced mortality by antitissue factor immunization," Arch. Surg., 1996, 131:1273-1278	
	38	Dahlback, "Inherited Thrombophilia: Resistance to Activated Protein C as a Pathogenic Factor of Venous Thromboembolism," Blood, 1995, 85:607-614	
	39	Database EMBL, "Coagulation factor VII (EC 3.4.21.21)(Serum prothrombin conversion accelerator)," "Bovine Factor VII. Its purification and complete amino acid sequence," ID FA7_BOVIN, August 1, 1991 (3 pages)	
	40	"Docking of Tissue Factor and Factor VIIa Initiates Blood Coagulation," at http://www.sdsc.edu/IOTW/week46.96/ (1996)	
	41	Esmon et al., "Isolation of a membrane-bound cofactor for thrombin-catalyzed activation of protein C," J. Biol. Chem., 1982, 257:859-864	

Examiner Signature	/Samuel Liu/	Date Considered	07/13/2009
--------------------	--------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Substitute for form 1449A-B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)	Complete if Known	
	Application Number	10/549,506
	Filing Date	July 7, 2006
	First Named Inventor	Kim Vilbourn Andersen
	Group Art Unit	1653
	Examiner Name	Not yet assigned
	Attorney Docket Number	0272us310

42	Evans, Jr. and Nelsestuen, "Importance of cis-Proline 22 in the Membrane-Binding Conformation of Bovine Prothrombin," <i>Biochemistry</i> , 1996, 35:8210-8215
43	Evans and Nelsestuen, "Importance of Cis-Proline 22 and the Aromatic Stack (Residues 41-45) for Prothrombin-Membrane Binding," <i>Protein Sci.</i> , 1996, 5(Suppl. 1):163, Abstract #606-S
44	Felgner et al., "Lipofection: a highly efficient, lipid-mediated DNA-transfection procedure," <i>Proc. Natl. Acad. Sci. USA</i> , 1987, 84:7413-7417
45	Fiore et al., "The biochemical basis for the apparent defect of soluble mutant tissue factor in enhancing the proteolytic activities of factor VIIIa," <i>J. Biol. Chem.</i> , 1994, 269:143-149
46	Freedman et al., "Identification of the phospholipid binding site in the vitamin K-dependent blood coagulation protein factor IX," <i>J. Biol. Chem.</i> , 1996, 271(27):16227-16236
47	Furie and Furie, "The molecular basis of blood coagulation," <i>Cell</i> , 1988, 53:505-518
48	Guo et al., "Protein Tolerance to random amino acid change," <i>Proc. Natl. Acad. Sci.</i> 101(25):9205-9210 (2004)
49	Han et al., "Isolation of a protein Z-dependent plasma protease inhibitor," <i>Proc. Natl. Acad. Sci. USA</i> , 1998, 95:9250-9255
50	He et al., "Expression and functional characterization of chimeras between human and bovine vitamin-K-dependent protein-S-defining modules important for the species specificity of the activated protein C cofactor activity," <i>Eur. J. Biochem.</i> , 1995, 227:433-440
51	Hedner et al., "Recombinant Activated Factor VII in the Treatment of Bleeding Episodes in Patients with Inherited and Acquired Bleeding Disorders," <i>Transfus. Med. Rev.</i> , 1993, 7:78-83
52	Hope et al., "Production of Large Unilamellar Vesicles by a Rapid Extrusion Procedure. Characterization of Size Distribution, Trapped Volume and Ability to Maintain a Membrane Potential," <i>Biochem. Biophys. Acta</i> , 1985, 812:55-65
53	Hoskins et al., "Cloning and characterization of human liver cDNA encoding a protein S precursor," <i>Proc. Natl. Acad. Sci. USA</i> , 1987, 84:349-353
54	Huang, "Studies on Phosphatidylcholine Vesicles. Formation and Physical Characteristics," <i>Biochemistry</i> , 1969, 8:344-352
55	Humphries et al., "Chemical methods of protein synthesis and modification," <i>Curr. Opin. Biotechnol.</i> , 1991, 2(4):539-543
56	Jurlander et al., "Recombinant Activated Factor VII (rFVIIa): Characterization, Manufacturing, and Clinical Development," <i>Semin. Thromb. Hemos.</i> , 2001, 27(4):373-383
57	Leff, "Genetically Stripped-Down Factor VIII Corrects Bleeding Disorder in Hemophilic Mice," <i>BioWorld Today</i> , 1997, 8(209):1,6
58	Lu and Nelsestuen, "Dynamic Features of Prothrombin Interaction with Phospholipid Vesicles of Different Size and Composition: Implications for Protein - Membrane Contact," <i>Biochemistry</i> , 1996, 35:8193-8200
59	Lu and Nelsestuen, "The prothrombinase reaction: "mechanism switching" between Michaelis-Menten and non-Michaelis-Menten behaviors," <i>Biochemistry</i> , 1996, 35:8201-8209
60	Martinez et al., "Undercarboxylation of Vitamin K-Dependent Proteins: Occasionally Severe, Possibly Universal," <i>Proceedings of the 49th ASMS Conference on Mass Spectrometry and Allied Topics</i> , May 27-31, 2001, Chicago, Illinois, 2 pgs.
61	Matsubara et al., "A receptor tyrosine kinase, Sky, and its ligand Gas 6 are expressed in gonads and support primordial germ cell growth or survival in culture," <i>Dev. Biol.</i> , 1996, 180:499-510
62	Mayer et al., "Prothrombin Association with Phospholipid Monolayers," <i>Biochemistry</i> , 1983, 22(2):316-321
63	Mayer, "Ultra-early hemostatic therapy for intracerebral hemorrhage," <i>Stroke</i> 2003, 34:224-229
64	McDonald et al., "Comparison of Naturally Occurring Vitamin K-dependent Proteins: Correlation of

Examiner Signature	/Samuel Liu/	Date Considered	07/13/2009
--------------------	--------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Substitute for form 1449A-B/PTO

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Application Number	10/549,506
Filing Date	July 7, 2006
First Named Inventor	Kim Vilbour Andersen
Group Art Unit	1653
Examiner Name	Not yet assigned
Attorney Docket Number	0272us310

		Amino Acid Sequences and Membrane Binding Properties Suggests a Membrane Contact Site," Biochemistry, 1997, 36:5120-5127	
65		McDonald et al., "Ionic Properties of Membrane Association by Vitamin K-Dependent Proteins: The Case for Univalency," Biochemistry, 1997, 36(50):15589-15598	
66		Morrissey et al., "Quantitation of Activated Factor VII Levels in Plasma Using a Tissue Factor Mutant Selectively Deficient in Promoting Factor VII Activation," Blood, 1993, 81(3):734-744	
67		Muir et al., "The chemical synthesis of proteins," Curr. Opin. Biotechnol., 1993, 4(4):420-427	
68		Nakagaki et al., "Initiation of the Extrinsic Pathway of Blood Coagulation: Evidence for the Tissue Factor Dependent Autoactivation of Human Coagulation Factor VII," Biochemistry, 1991, 30:10819-10824	
69		Nelsestuen et al., "Membrane association with multiple calcium ions: vitamin-K-dependent proteins, annexins and pentraxins," Current Opinion in Structural Biology 9:433-437 (1999)	
70		Nelsestuen, "Enhancement of Vitamin-K-Dependent Protein Function by Modification of the gamma-Carboxyglutamic Acid Domain: Studies of Protein C and Factor VII," Trends Cardiovasc. Med. 9(6):162-167 (1999)	
71		Nelsestuen et al., "Vitamin K-Dependent Proteins," in 58 VITAMINS AND HORMONES: ADVANCES IN RESEARCH AND APPLICATIONS (Gerald Litwack ed., Academic Press, 2000), pp. 355-389	
72		Nelsestuen et al., "Equilibria Involved in Prothrombin- and Blood Clotting Factor X-Membrane Binding," Biochemistry, 1977, 16(19):4164-4171	
73		Nelsestuen and Suttie, "Properties of Asialo and Aglycoprothrombin," Biochem. Biophys. Res. Commun., 1971, 45:198-203	
74		Nicolaes et al., "A prothrombinase-based assay for detection of resistance to activated protein C," Thromb. Haemost., 1996, 76:404-410	
75		Nicolaisen et al., "Immunological aspects of recombinant factor VIIa (rFVIIa) in clinical use," Thromb. Haemost., 1996, 76:200-204	
76		Okafuji et al., EMBL Data Library, Accession No. S18994, Sept. 10, 1999 (protein C activated precursor, sequence) (Score Search)	
77		Perera et al., "Trans-cis Isomerization of Proline 22 in Bovine Prothrombin Fragment 1: A Surprising Result of Structural Characterization," Biochemistry, 1998, 37:10920-10927	
78		Petersen et al., "Quenching of the amidolytic activity of one-chain tissue-type plasminogen activator by mutation of lysine-416," Biochemistry, 1990, 29:3451-3457	
79		Petrovan et al., "Residue Met ¹⁵⁶ contributes to the labile enzyme conformation of coagulation factor VIIa," J. Biol. Chem. 2001, 276(9):6616-6620	
80		Ratcliffe et al., "The Importance of Specific γ-Carboxyglutamic Acid Residues in Prothrombin," J. Biol. Chem., 1993, 268(32):24339-24345	
81		Resnick and Nelsestuen, "Prothrombin-Membrane Interaction. Effects of Ionic Strength, pH, and Temperature," Biochemistry, 1980, 19(13):3028-3033	
82		Rezaie and Esmon, "The function of calcium in protein C activation by thrombin and the thrombin-thrombomodulin complex can be distinguished by mutational analysis of protein C derivatives," J. Biol. Chem., 1992, 267:26104-26109	
83		Sakai et al., "The γ-Carboxyglutamic Acid Domain of Human Factor VIIA is Essential for Its Interaction with Cell Surface Tissue Factor," J. Biol. Chem., 1990, 265(4):1890-1894	
84		Schmidel et al., "Organization of the Human Protein S Genes," J. Biol. Chem., 1990, 265(34):7845-7852	
85		Schulman et al., "Feasibility of using recombinant factor VIIa in continuous infusion," Thromb. Haemost., 1996, 75(3):432-436	
86		Schwalbe et al., "Protein Structural Requirements and Properties of Membrane Binding by γ-Carboxyglutamic Acid-containing Plasma Proteins and Peptides," J. Biol. Chem., 1989, 264:20288-	

Examiner Signature	/Samuel Liu/	Date Considered	07/13/2009
--------------------	--------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Substitute for form 1449A-B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)	Complete if Known	
	Application Number	10/549,506
	Filing Date	July 7, 2006
	First Named Inventor	Kim Vilbour Andersen
	Group Art Unit	1653
	Examiner Name	Not yet assigned
	Attorney Docket Number	0272us310

	20296	
87	Seffernick et al., "Melamine Deaminase and Atrazine Chlorohydrolase: 98 Percent Identical but Functionally Different," J. Bacteriol. 183(8):2405-2410 (2001)	
88	Seshadri et al., "Differences in the Metal Ion Structure between Sr- and Ca-Prothrombin Fragment 1," Biochemistry, 1994, 33:1087-1092	
89	Shen et al., "Enhancing the Activity of Protein C by Mutagenesis to Improve the Membrane-Binding Site: Studies Related to Proline 10," Biochemistry, 1997, 36(51):16025-16031	
90	Shen et al., "Enhancement of Human Protein C Function by Site-directed Mutagenesis of the γ -Carboxyglutamic Acid Domain," J. Biol. Chem., 1998, 273(47):31086-31091	
91	Smirnov et al., "A Chimeric Protein C Containing the Prothrombin Gla Domain Exhibits Increased Anticoagulant Activity and Altered Phospholipid Specificity," J. Biol. Chem., 1998, 273(15):9031-9040	
92	Thariath et al., "Highly conserved residue arginine-15 is required for the Ca^{2+} -dependent properties of the γ -carboxyglutamic acid domain of human anticoagulation Protein C and activated Protein C," Biochem. J., 1997, 322:309-315	
93	Thim et al., "Amino Acid Sequence and Posttranslational Modification of Human Factor VIIa from Plasma and Transfected Baby Hamster Kidney Cells," Biochemistry, 1988, 27:7785-7793	
94	Thomsen et al., "Pharmacokinetics of recombinant factor VIIa in the rat - a comparison of bio-, immuno- and isotope assays," Thromb. Haemost., 1993, 70(3):458-464	
95	Vallette et al., "Construction of mutant and chimeric genes using the polymerase chain reaction," Nucleic Acids Res., 1989, 17(2):723-733	
96	Vrana et al., "Expression of tissue factor in tumor stroma correlates with progression to invasive human breast cancer: paracrine regulation by carcinoma cell-derived members of the transforming growth factor beta family," Cancer Res., 56:5063-5070 (1996)	
97	Weber et al., "Modifications of Bovine Prothrombin Fragment 1 in the Presence and Absence of $\text{Ca}(\text{II})$ Ions," J. Biol. Chem., 1992, 267(7):4564-4569	
98	Wei et al., "Kinetic and Mechanistic Analysis of Prothrombin-Membrane Binding by Stopped-Flow Light Scattering," Biochemistry, 1982, 21:1949-1959	
99	Wells, "Additivity of Mutational Effects in Proteins," Biochem. 29(17):8509-8517 (1990)	
100	Welsch et al., "Chemical Modification of Prothrombin Fragment 1: Documentation of Sequential, Two-Stage Loss of Protein Function," Biochemistry, 1988, 27:4933-4938	
101	Welsch and Nelsestuen, "Amino-terminal alanine functions in a calcium-specific process essential for membrane binding by prothrombin fragment 1," Biochemistry, 1988, 27:4939-4945	
102	Yan et al., "Characterization and Novel Purification of Recombinant Human Protein C from Three Mammalian Cell Lines," Bio/Technology, 1990, 8:655-661	
103	Zhang et al., "Role of Individual γ -Carboxyglutamic Acid Residues of Activated Human Protein C in Defining its In Vitro Anticoagulant Activity," Blood, 1992, 80(4):942-952	
104	Zwaal et al., "Lipid-protein interactions in blood coagulation," Biochimica et Biophysica Acta, 1998, 1376:433-453	

Examiner Signature	/Samuel Liu/	Date Considered	07/13/2009
--------------------	--------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.